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| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/518,817 | BAILEY ET AL. | |
| | Examiner | Art Unit | |
| | Venkataraman Balasubramanian | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/22/2006.
2. ☒ The allowed claim(s) is/are 9 and 11-16.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicants' response, which included amendment to claim 11 and cancellation of claims 1-8 and 10, filed on 5/22/2006, is made of record. Claims 9 and 11-16 are now pending. In view of applicants' response, all 112 second paragraph rejections have been obviated. In addition, prior art rejection over WO 03/020278 is deemed as obviated in view of applicants' earlier foreign priority date 6/24/2002 as compared to the effective priority date of 8/29/2002 of WO 03/020278.

The pharmaceutical composition and method of use of compound of formula I shown in claims 9 and 11, namely, variously substituted- 2-cyano-pyrimidines embraced in the instant claims 9 and 11 were not found to be anticipated or rendered obvious by the prior art of record. Although the reference Altmann et al., US 2004/0249153 (equivalent to WO 03/020278), teaches variously substituted 2-cyano-pyrimidine compound, it is not a competent prior art in view of applicants' foreign priority noted above. In addition, although the R^1 and R of instant claims overlap when $Y = O$ or NR^{10} and $p=0$, with $NH-R_2$ and R of Altmann et al., there is no direct overlap of A of instant claims with R_1 of Altmann et al. The closest overlap is a homolog compound, when $A = CHR^3R^2$ wherein R^3 is H and R^2 is C_1 alkyl substituted with NR^4 where R^4 is cycloalkyl (that is $A = CH_2CH_2NH$ -cycloalkyl) in the instant claims with $R = CH_2NH$ -cycloalkyl. But the reference does not exemplify a compound with $R = CH_2NH$ -cycloalkyl and hence one trained in the art would not be able to select such a homolog compound and would not be motivated to make the homolog with the expectation that the homolog would share

the same use of the parent compound with out any guidance provided in the reference. Additional search in the related art area also did not yield any prior art teaching the pharmaceutical composition and method of use of compound of formula I embraced in the instant claims. Therefore, the examiner noted that the claims 9 and 11-16 would be in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

6/1/2006